

Interview Summary	Application No.	Applicant(s)	
	08/951,188	PRICE, DAVID H.	
	Examiner	Art Unit	
	David J Steadman	1652	

All participants (applicant, applicant's representative, PTO personnel):

(1) David Steadman.

(3) Brian Stanton.

(2) Ponnathapura Achutamurthy.

(4) Shelley P. M. Fussey.

Date of Interview: 27 July 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: claims rejected in latest office action.

Identification of prior art discussed: Marshall et al. (cited in the latest Office action) and Jones et al. (US Patent 6,284,456).

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

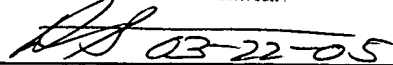
Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

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The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

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The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: This interview was conducted upon Ms. Fussey's request to discuss outstanding rejections in the latest Office action mailed March 19, 2004. Regarding the rejection under 35 USC 101, it was suggested that applicant insert "isolated" to indicate the hand of man in the invention. Regarding the written description rejection under 35 USC 112, first paragraph, no resolution was reached, however, it was agreed that claim language that would overcome the rejection could be negotiated at a later time. It is noted that Ms Fussey indicated that it was applicant's intention for the claims reciting "fragment" in conjunction with "comprising," i.e., claims 133-136, that the fragment is to be limited to only the fragment of claim 113. Brian Stanton suggested clarifying claim 136 by reciting a nucleic acid encoding a fusion protein instead of a distinct, selected nucleic acid coding region that encodes a distinct, selected peptide or protein sequence. Regarding the scope of enablement rejection, Examiner Steadman indicated that, after review of the evidence of record, the application was not enabling for the full scope of claimed variants. Applicant was questioned as to the evidence in the specification that would enable the full scope of the claims. Applicants indicated that the specification provided assays for determining those variants that have the desired biological activity and provided sequence alignments and guidance as to regions of homology to other proteins. It was decided that further review of the specification would be required to make a proper determination of this evidence. Applicants noted the US Patent 6,284,456 (the Jones Patent) recited a claim to a sequence nearly identical to SEQ ID NO:50 of the instant application and variants thereof that are broader than applicant's claims. This was noted, however, it was indicated that each application is examined on its own merits. Regarding the obviousness rejection, Ms. Fussey stated that the rejection is inconsistent with *In re Deuel* and *In re Bell*. it was noted that further discussion was required before making a determination on the merits of the rejection.

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	Examiner David J Steadman	Art Unit 1652	

All participants (applicant, applicant's representative, PTO personnel):

- (1) David Steadman. (3) Shelley P.M. Fussey.
 (2) Ponnathapura Achutamurthy. (4) ____.

Date of Interview: 03 August 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____.

Claim(s) discussed: claims rejected for scope of enablement/obviousness.

Identification of prior art discussed: Marshall et al. (cited in the latest Office action) and Jones et al. (US Patent 6,284,456).

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

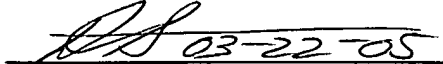
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Paragraph (b)

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Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: This telephonic interview is a follow-up to the interview conducted on July 27, 2004. After further consideration, it was decided that the obviousness rejection of the claims as being unpatentable in view of Marshall et al. should be withdrawn. It was further decided that the scope of enablement rejection should be maintained. After a review of the application, it was decided that the specification failed to enable the full scope of claimed variant polynucleotides. The examiner noted that no sequence alignments could be found in the specification. It was suggested that applicants submit any available evidence that would teach a skilled artisan where alterations to the encoding nucleic acid sequence can be made with an expectation of obtaining a polypeptide having the desired activity, for example, sequence alignments and references describing 3-D structures. Ms. Fussey expressed disagreement with the rejection and pointed out that the Jones Patent recited a claim to a nucleic acid sequence nearly identical to SEQ ID NO:50 of the instant application and that was broader than applicant's claims. The examiner reiterated that each case is examined on its merits. Ms. Fussey further indicated that she was not authorized to submit a response. Ms. Fussey requested that Examiner Steadman and Dr. Achutamurthy hold a meeting with Brian Stanton to express her concerns regarding the scope of enablement rejection.

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All participants (applicant, applicant's representative, PTO personnel):

(1) David J Steadman.

(3) Shelley P.M. Fussey.

(2) Deborah Reynolds.

(4) _____.

Date of Interview: 16 September 2004.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: claims rejected under 35 USC 112, first, scope of enablement.

Identification of prior art discussed: Jones et al.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

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Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: This interview is a follow-up to a telephonic interview conducted on August 10, 2004. The examiner indicated that all issues presented in the Office action mailed March 19, 2004 had been completely resolved or resolved to a level that could be negotiated at a later time. The interview focused on the scope of enablement rejection under 35 USC 112, first paragraph. The examiner reiterated that the evidence of record did not enable the full scope of claimed polynucleotides. The examiner suggested providing additional evidence that would guide a skilled artisan in the making of the full scope of variants that are encompassed by the claims with an expectation of obtaining an encoded polypeptide having the desired activity. Ms Fussey referred to the Jones Patent, stating that the Jones Patent recited claims that are much broader than applicant's claims. The examiner reiterated that the validity of issued US Patents cannot be discussed. Ms. Fussey inquired as to whether it was possible to re-send the action with a new mailing date. The examiner indicated that this is not consistent with Office policy. As one strategy for maintaining pendency, the examiner suggested submitting a notice of appeal..